I. Claims 1-29 and 36, drawn to a recombinant GAD-65 or proinsulin peptide, a method of assay using the peptide, and a composition classified in Class 530, Subclass 350 and Class 435, Subclass 7.1.

II. Claims 30-35, drawn to a method of treatment with a recombinant GAD-65 or proinsulin peptide classified in Class 514, Subclass 12.

In support of the present restriction requirement, the Examiner has alleged that the subject matter defined by the claims of the present invention represents two separate and distinct inventions. The Examiner has specifically alleged that "the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features."

As indicated, and in order to be fully responsive to the Examiner's requirements for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group I, Claims 1-29 and 36, directed to recombinant GAD-65 or proinsulin peptide, a method of assay using the peptide, and a composition.

Pursuant to 37 C.F.R. §§1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

A requirement for restriction presupposes an analysis of the subject application in light of the rules governing this practice, i.e., 37 C.F.R. §1.499 and PCT Rules 13.1 and 13.2. PCT Rule 13.1, first sentence, states: "The international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention")." (Emphasis added.)

Applicants submit that Groups I and II are not even distinct as the Examiner has alleged, but rather represent one single inventive concept warranting examination in a single application. Group I is directed to a recombinant GAD-65 or peptide, a method of assaying the reactivity of a subject to Insulin Dependent Diabetes Mellitus using the peptide; and a composition. Group II is directed to a method for treating a subject with the peptide of Group I. Groups I and II are, at least, related as product (recombinant GAD-65 peptide) and method of using the product (in vivo treatment using the peptide). Therefore, these embodiments clearly define one single, general inventive concept.

PCT Rule 13.2 defines claims of different categories permitted by Rule 13.1. One permissible combination is as follows:

> (I) In addition to an independent claim for a given product, the inclusion in the same international application of an independent claim for a process specially adapted for the manufacture of the said product, and the inclusion in the same international application of an independent claim for the use of said product. (Emphasis added.)

In the present circumstances, the product of Group I is specifically employed in the method of Group II. Accordingly, Groups I and II should be examined in a single application.

Furthermore, Applicants respectfully suggest that, in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs

(GATT), Applicants are required to conduct simultaneous prosecution, as here, requiring excessive cost or the loss or compromise of the term of the related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations.

The Court of Appeals for the Federal Circuit has declined to hold that §121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle mbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986); and in Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990) that court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights

are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public's interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

The Examiner justified the restriction requirement in this case by reference to the different subclasses of the Patent and Trademark Office classification system in which the two groups of claims would allegedly be classed. This basis fails to justify the restriction requirement in this application.

Reliance on the classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicant's unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the subclass(es) with which the Examiner associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a

shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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